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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

17 IN RE: Bard IVC Filters Products Liability
18 Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS' RESPONSE IN
OPPOSITION TO PLAINTIFF'S
MOTION FOR
RECONSIDERATION**

21 (Assigned to the Honorable David G.
Campbell)

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1 Plaintiff's Motion for Reconsideration (Dkt. No. 10873) is based upon a false
 2 premise. While Plaintiff claims there are two reports of "death from filter migration to
 3 heart in Eclipse patients," (Pl.'s Mot. at 4 (citing Complaint File Nos. 313635 and
 4 354264)), a close inspection of those two complaints confirms ***they are not cephalad***
 5 ***migration-related deaths***, nor are they at all similar to the reports of Recovery Filter
 6 cephalad migration deaths that Bard received in 2004 and 2005. Indeed, a review of the
 7 complaint files confirms that for one of the events cited by Plaintiff (No. 313635), the
 8 Eclipse Filter likely saved the patient's life, and only after a competitor filter was
 9 subsequently implanted did the patient unfortunately pass away. For the other event cited
 10 (No. 354264), the Eclipse Filter migrated only to the "proximity of the right atrium" (i.e.,
 11 not fully lodged in the patient's heart), the cause of the patient's death was thought to be
 12 pulmonary embolism, and the doctor involved in the case did not believe that the patient's
 13 death was "related" to the filter.

14 With Plaintiff's false premise exposed, her Motion for Reconsideration becomes
 15 nothing more than a rearguing of the points she made in her prior Response Brief (Dkt.
 16 No. 10701) and during the argument concerning this issue on April 13, 2018. For the
 17 reasons this Court has already articulated, (*see* Dkt. No. 10819, at 3-6), Plaintiff's
 18 arguments concerning the alleged relevancy of Recovery Filter cephalad migration-related
 19 deaths should be rejected.¹

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21 ¹ This Court recently stated that "[a] motion for reconsideration will be denied 'absent a
 22 showing of manifest error or a showing of new facts or legal authority that could not have
 23 been brought to [the Court's] attention earlier with reasonable diligence.'" *Salt River
 24 Project Agric. Improvement & Power Dist. v. Trench France SAS*, No. CV-17-01468-
 25 PHX-DGC, 2017 WL 6554860, at *1 (D. Ariz. Dec. 22, 2017) (quoting LRCiv 7.2(g)(1);
 26 citing *Carroll v. Nakatani*, 342 F.3d 934, 945 (9th Cir. 2003)). As a result, there are only
 27 "four circumstances where a motion for reconsideration will be granted: (1) the moving
 28 party has discovered material differences in fact or law from those presented to the Court
 at the time of its initial decision, and the party could not previously have known of the
 factual or legal differences through the exercise of reasonable diligence; (2) material
 factual events have occurred since the Court's initial decision; (3) there has been a
 material change in the law since the Court's initial decision; or (4) the moving party makes
 a convincing showing that the Court failed to consider material facts that were presented
 to the Court at the time of its initial decision." *Nicole-Pickett v. Wells Fargo Bank, N.A.*,
 No. CV-16-03262-PHX-DGC, 2016 WL 7187988, at *1 (D. Ariz. Dec. 12, 2016). None
 of these circumstances occurred here, and Plaintiff provide no reason that these complaint

1 This is an Eclipse Filter case. The jury will be asked to decide whether *the Eclipse*
 2 is defective and unreasonably dangerous, and whether Bard provided appropriate and
 3 adequate warnings *concerning the Eclipse*. But, Plaintiff would rather try this case as a
 4 referendum on the Recovery Filter. Indeed, Plaintiff's Motion for Reconsideration once
 5 again makes clear her desire to inflame the jury by attempting to inject into this case
 6 irrelevant evidence regarding Recovery cephalad migration-related deaths. This Court
 7 correctly found such evidence to have, at most, "marginal relevancy" in this Eclipse case.
 8 (Dkt. No. 10819, at 5.) Bard respectfully requests that this Court reconfirm its conclusion
 9 that evidence of Recovery cephalad migration deaths should be excluded from this Eclipse
 10 case pursuant to Rule 403 because the probative value, if any, of such evidence is
 11 substantially outweighed by the prejudicial effect.

12 ARGUMENT AND CITATION TO AUTHORITIES

13 A. Plaintiff Still Cannot Identify Any Reports of Death Caused by the Cephalad 14 Migration of a G2, G2X, or Eclipse Filter.

15 Plaintiff requested leave to file her Motion for Reconsideration ostensibly because
 16 she claims to have identified deaths allegedly caused by the cephalad migration of a Bard
 17 G2, G2X, or Eclipse Filter. Bard's position has consistently been that Bard's later
 18 generation IVC filters largely resolved the problem of cephalad migration, and that,
 19 notwithstanding having sold more than 180,000 G2/G2X Filters and more than 66,000
 20 Eclipse Filters, and producing the relevant internal complaint files regarding those
 21 devices to Plaintiff, Bard was unaware of any report of a G2, G2X, or Eclipse Filter
 22 migrating to a patient's heart and allegedly causing the patient's death. Bard's position is
 23 confirmed by Plaintiff's Motion for Reconsideration, including by the information

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 25 files, produced to Plaintiff two years ago, "could not have been brought to the Court's
 26 attention earlier with reasonable diligence." "No motion for reconsideration of an Order
 27 may repeat any oral or written argument made by the movant . . . that resulted in the
 28 Order," and it is not "the time to ask the Court to rethink what it has already thought." L.R. Civ. 7.2(g)(1); *Nicole-Pickett*, 2016 WL 7187988 at *1. As a result, Plaintiff's motion should be denied.

1 provided in Plaintiff's Exhibit B, which purports to be a "representative summary" of
2 cephalad migrations involving Bard's later generation filters. Specifically, a close
3 inspection of the two death-related complaints identified in Plaintiff's Exhibit B --
4 Complaint File Nos. 313635 and 354264 -- reveals that, contrary to Plaintiff's claims, the
5 complaints are not reports of "death from filter migration to heart in Eclipse patients."
6 (Pl.'s Mot. at 4 (citing Complaint File Nos. 313635 and 354264).)

7 **Complaint No. 313635:** Plaintiff claims that this report discusses "death from
8 filter migration to heart." (Pl.'s Mot. at 4.) Plaintiff's characterization of this report is
9 simply not accurate.

10 The Complaint Record Detail Report, attached as a portion of Exhibit B to
11 Plaintiff's Motion (*see* Pl.'s Mot., Ex. B, at 33-38 (Bates labeled BPV-COMP-00025535
12 to 25540), demonstrates that Complaint No. 313635 *is not* a report of death caused by
13 the cephalad migration of an Eclipse Filter, as Plaintiff claims. In fact, the complaint file
14 confirms that the Eclipse Filter likely initially saved the patient's life. [REDACTED]

15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED] [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]

24 _____

25 ² [REDACTED]
26 [REDACTED]
27 [REDACTED]
28 [REDACTED] [REDACTED]

1

2 [REDACTED]

3 Thus, according to the complaint file, the patient did not die “from filter migration
4 to heart,” as Plaintiff claims. [REDACTED]

4

5 [REDACTED].³

6 **Complaint No. 354264:** Again, Plaintiff claims that this report discusses “death
7 from filter migration to heart.” (Pl.’s Mot. at 4.) Again, Plaintiff’s characterization of this
8 report is simply not accurate.

9 The Complaint Record Detail Report, attached as a portion of Exhibit B to
10 Plaintiff’s Motion (*see* Pl.’s. Mot., Ex. B, at 72-76 (Bates labeled BPV-COMP-00026440
11 to 26444), demonstrates that Complaint No. 354264 *is not* a report of death caused by
12 the cephalad migration of an Eclipse Filter, as Plaintiff claims. The complaint file notes
13 [REDACTED]

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22 ³ Plaintiff tacitly recognizes that this complaint is dissimilar from the Recovery Filter
23 cephalad migration deaths -- where the entire device *and* a large clot burden migrated to a
24 patient’s heart, allegedly causing death (*see, e.g.*, Pl.’s Mot., Ex. N, at 6-7 (Bates labeled
25 BPV-17-01-00153663 to 153664 (noting that in first report of Recovery cephalad
26 migration-related death, the filter was encased in clot and was found to have migrated to
27 the patient’s right atrium))) -- but she tries to find similarities with the Eclipse events by
28 arguing that both “were associated with large clot burdens.” (*See* Pl.’s Mot. at 6 n.3.) That the Recovery and Eclipse death events both involved “large clot burdens” only tells a
small portion of the story. Indeed, a case involving a migration of a large clot and a Bard
filter to the heart is very different from a case involving a Bard filter that stopped a clot
from reaching a patient’s heart, the Bard filter and clot being removed, and then a
competitor filter implanted, with the patient later passing away due to another pulmonary
embolism. Plaintiff’s attempt to claim that these two types of events are identical or
substantially similar strains credulity.

1 Motion, it was never determined that this patient died “from filter migration to heart,” as
 2 Plaintiff claims. [REDACTED]
 3 [REDACTED]
 4 [REDACTED]

5 **Remaining Complaints Identified in Plaintiff’s Exhibit B:** Plaintiff also
 6 identifies additional purported non-fatal cephalad migration events associated with the
 7 G2, G2X, and Eclipse Filters. But Bard has never argued that its later generation IVC
 8 filters are 100% free from the risk of cephalad migration. To the contrary, Bard has
 9 consistently argued that the risk of cephalad migration is a risk associated with all makes
 10 and models of IVC filters, and that reports of cephalad migration of filters to the heart
 11 have been associated with many different filters, including the SNF and competitor
 12 filters. That is why cephalad migration is described in the SIR Guidelines, and why Bard
 13 warns of such migration in each and every one of its retrievable filter IFUs.

14 Bard’s position is that its subsequent generation IVC filters largely addressed and
 15 resolved the complication of cephalad migration as compared to the Recovery. Notably,
 16 Plaintiff presents no evidence or data suggesting that cephalad migration occurred with
 17 Bard’s subsequent generation filters anywhere near the same frequency as with the
 18 Recovery. Instead, Plaintiff’s counsel admitted during argument that “there is not a lot of
 19 cephalad migration” with Bard’s later generation filters, and that Bard’s later generation
 20 filters “by and large” “fix[ed]” cephalad migration. (4/13/18 Pretrial Conference Trans.
 21 at 14:9-10; 15:19-21.)

22 Finally, most of the non-death cephalad migrations identified in Plaintiff’s Exhibit
 23 B do not involve migrations to the heart (e.g., Complaint File Nos. 291446, 239963,
 24 248122, and 260851), or they involve circumstances where the filter legs did not fully
 25 open and deploy at implant, events which are unlike the Recovery Filter cephalad
 26 migration-related deaths (e.g., Complaint File Nos. 250927⁴, 273135⁵, and 283282). In

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 28 ⁴ Plaintiff’s narrative in her “Representative Summary” fails to note [REDACTED]

fact, the only non-Recovery Filter cephalad migration event identified in Plaintiff's Exhibit B, Complaint File No. 383261, [REDACTED]
[REDACTED]
[REDACTED] (Pl.'s' Mot., Ex. B, at 123 (Bates labeled BPV-COMP-00027608).)

* * *

As demonstrated above, and contrary to Plaintiff's argument, Bard's representations to this Court that it is unaware of any report of a G2, G2X, or Eclipse Filter migrating to a patient's heart and allegedly causing the patient's death remains 100% accurate. Plaintiff has gone to great lengths to try to argue that two reports out of the numerous patients who received G2/G2X/Eclipse Filters (out of more than 246,000 sold) who subsequently passed away are examples of "death from filter migration to heart," (*see* Pl.'s Mot. at 4), but those efforts have proven fruitless. The two Eclipse death events are simply not examples of patient death due to an alleged cephalad migration of the filters to the patients' hearts.

Because the fundamental premise of Plaintiff's Motion is proven to be false, and there are still no confirmed reports of cephalad migration to the heart allegedly causing death associated with Bard's later generation filters, the logic that underlies this Court's original ruling remains fully sound, and Plaintiff's Motion for Reconsideration should be denied.

B. Any Marginal Probative Value of Evidence Concerning Recovery Filter Cephalad Migration-Related Deaths Is Substantially Outweighed by the Risk of Unfair Prejudice.

This Court previously found that the "marginal relevanc[e]" of evidence

[REDACTED]" (Pl.'s' Mot., Ex. B, at 154 (Bates labeled TW_COMPLAINT_004754).)

⁵ Plaintiff's narrative in her "Representative Summary" fails to note that [REDACTED]

(See Pl.'s' Mot., Ex. B, at 187 (Bates labeled TW_COMPLAINT_005181).)

1 concerning Recovery Filter cephalad migration death is “substantially outweighed by the
 2 danger of unfair prejudice.” (Dkt. No. 10819, at 5.) That marginal relevance remains
 3 unchanged despite Plaintiff’s Motion for Reconsideration, given the Court’s fundamental
 4 premise -- i.e., that there are no confirmed reports of a G2, G2X, or Eclipse Filter
 5 migrating to a patient’s heart and allegedly causing the patient’s death -- remains
 6 accurate.

7 Moreover, Plaintiff’s Motion confirms the unfairly prejudicial impact that
 8 evidence of Recovery cephalad migration death would have on this Eclipse case. For
 9 example, Plaintiff argues that testimony from Dr. Gary Cohen (a physician who **did not**
 10 treat Ms. Jones) is “powerful evidence that Bard knew about risks with its product [i.e.,
 11 the Recovery] but failed to tell physicians about it, including the fact that the Recovery
 12 had been placed on a QC hold.” (Pl.’s Mot. at 9 n. 6.) Using such testimony to argue that
 13 Bard failed to warn about the Recovery Filter, in a case involving the Eclipse Filter,
 14 would unfairly prejudice Bard and would confuse the issues. It would inappropriately
 15 invite the jury to find that Bard has a propensity to fail to warn doctors about all of its
 16 products, including the Eclipse, which is a violation of Federal Rule of Evidence, Rule
 17 404(a)&(b). Plaintiff’s use of such testimony would also run afoul of this Court’s prior
 18 conclusion that “Bard’s general failure to disclose problems with the Recovery is not
 19 relevant to design of the G2 and is only marginally relevant, if relevant at all, to Bard’s
 20 alleged failure to warn claim with respect to the G2. The danger of unfair prejudice from
 21 these questions substantially outweighs any probative value.” (Dkt. No. 10438.)

22 Similarly, Plaintiff seeks to inappropriately use evidence of Recovery Filter
 23 cephalad migration death root cause analyses to try to prove that Bard conducted
 24 inadequate root cause analyses with its Eclipse Filter. (*See, e.g.*, Pl.’s Mot. at 4.)
 25 Plaintiff also seeks to use evidence of Recovery cephalad migration deaths to prove that
 26 Bard, “in the face of continued cephalad migrations,” inappropriately “reevaluat[ed] its

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1 design once again within months of the Eclipse launch.”⁶ Again, using such evidence to
 2 try to prove propensity is prohibited by Rule 404(a)&(b).

3 At bottom, this Court previously recognized the inherent risk of unfair prejudice
 4 that would be presented if evidence of Recovery Filter cephalad migration-related deaths
 5 is injected into this Eclipse case. (*See, e.g.*, Dkt. No. 10438, at 5-6.) Plaintiff’s Motion
 6 only confirms that risk. Because Plaintiff has not presented any new evidence
 7 demonstrating the relevance of evidence of cephalad migration death, this Court should
 8 confirm its finding that any probative value of such evidence is substantially outweighed
 9 by the risk of unfair prejudice.

10 **C. Evidence of Recovery Cephalad Migration-Related Deaths Can Be Removed
 11 From This Case.**

12 Plaintiff’s concern that evidence of Recovery Filter cephalad migration-related
 13 deaths cannot “reasonably be extracted” from the “overall complication evidence” is
 14 overblown. The parties can review their proposed deposition designations and documents
 15 that concern Recovery issues, and edit or redact the materials as necessary to remove
 16 references to Recovery cephalad migration-related deaths. Thus, Plaintiff’s concern can
 17 be addressed by careful review and editing.⁷

18 Additionally, Plaintiff has substantial non-Recovery and non-death migration
 19 evidence at her disposal. Indeed, Bard has produced to Plaintiff millions of pages of

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 21 ⁶ The factual premise of Plaintiff’s argument -- that Bard sought to “redesign” the Eclipse
 22 within months of its release -- is simply not accurate. As Bard’s internal documents and
 communications to FDA make clear, Bard simultaneously developed the Eclipse,
 Meridian, and Denali Filters at the time.

23 ⁷ Regarding Plaintiff’s Exhibit O, Plaintiff has not met and conferred regarding
 24 application of the Court’s April 18, 2018, Order excluding Recovery Filter migration-
 25 related deaths to deposition designations. In an effort to meet the then April 20, 2018,
 26 deadline to submit all deposition designations and objections, counsel for Bard attempted
 27 to identify deposition testimony and exhibits impacted by the Court’s ruling on an
 28 expedited basis. Defense counsel’s attempt to quickly identify testimony impacted by the
 Court’s ruling included providing Plaintiff with Defendant’s objection language to insert
 into the transcript wherever Plaintiff did not agree to strike certain testimony. Defense
 counsel received no counter-proposals and heard nothing further from Plaintiff’s counsel
 until various excerpts appeared in Plaintiff’s Exhibit O. Defendants stand ready to meet
 and confer regarding the implementation of the Court’s ruling to deposition designations.

1 documents in this MDL, including the complete Eclipse design files, regulatory
 2 correspondence files, marketing, and post-market surveillance materials. Additionally,
 3 Plaintiff's allegations regarding the absence of Recovery complication or migration-
 4 related evidence outside the context of Recovery cephalad migration deaths are simply
 5 inaccurate. Contrary to Plaintiff's claim that there are "no documents reviewing or
 6 analyzing Recovery migrations independent of the deaths," (Pl.'s Mot. at 7), Bard has
 7 produced voluminous such documents, including evidence regarding the Asch clinical
 8 study and investigation into the reported cephalad migration from that trial (an issue that
 9 had some prominence in the Booker trial), post-market Recovery migration resistance
 10 assessments and testing, and the individual non-death Recovery cephalad migration
 11 complaint files produced by Bard in this case (and which include their own root cause
 12 analyses). Similarly, Bard has produced comprehensive investigations, failure
 13 investigation reports, and health hazard evaluations concerning Recovery Filter fracture
 14 (fracture being the complication that Ms. Jones actually experienced), and G2 Filter
 15 caudal migration. Accordingly, Plaintiff has substantial non-cephalad migration-related
 16 death evidence to fairly try her case.⁸ And, as this Court concluded, Plaintiff may rely on
 17 her experts to attempt to prove her case without resorting to the unfairly prejudicial
 18 evidence of Recovery cephalad migration-related deaths. (*See, e.g.*, Dkt. No. 10438, at
 19 4.)

20 CONCLUSION

21 For the stated above, Bard respectfully requests that this Court deny Plaintiff's
 22 Motion for Reconsideration.

23
 24 s/Richard B. North, Jr.
 25 Richard B. North, Jr.
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 Matthew B. Lerner

26 _____
 27 ⁸ Indeed, Plaintiff attached to her Motion for Reconsideration various documents
 28 concerning non-Recovery cephalad migration-related death issues that she feels support
 her claims. (*See, e.g.*, Pl.'s Mot., Exs. D, E, and H.)

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of April, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.